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(54) IMPROVEMENTS IN OSTOMY BAG

(71) We, KINGSDOWN MEDICAL CONSULTANTS LIMITED, a British Company, of Blackfriars House, 19 New Bridge Street, London EC4V 6BY, do hereby declare

the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a coupling for joining an ostomy bag to a pad or surgical dressing. Ostomy bags are usually secured to a pad or surgical dressing which contacts the user's skin and surrounds the stoma. There is a need for a coupling between pad and bag which allows the bag to be readily removed when necessary, and replaced by a clean, empty bag. At the same time, it is essential that the coupling should be a secure one, and prevent leakage particularly of liquids and gases.

Efforts have been made, see for example the proposal in British Patent Specification No. 1 021 145 published in 1966, to provide a connector whereby the bag can be readily removed and replaced. But this arrangement involves two separate operations, firstly one must unscrew the connector which carries the bag from the connector which is secured to the body and this involves a risk of leakage as it is necessary to invert the bag. Also it is an awkward operation. It will be appreciated that at this time the bag is full or partly-full of bodily waste products, and manipulation of the coupling will be an unpleasant operation even if, as is often not the case, the user has a high degree of dexterity.

British Patent Specification 1 099 455 discloses an appliance in which one ring co-operates with a second part-ring which is used to trap the neck of a bag when the two rings are inter-engaged with the bag mouth between them. If adequate security against leakage is to be provided, it is necessary that the two rings should be a tight fit; however this makes it difficult for the user to pull off the part-ring. As the part-ring is pulled off, there is the probability that the security of attachment of the first ring to the surgical dressing, or of the dressing to the skin of the wearer, will be impaired. This may also cause discomfort to the wearer.

In British Patent Specification No. 1212904, a complicated approach has been adopted. A clamping ring which has a ring-closing lever associated therewith embraces a mouth of a bag and causes the clamping ring to clamp the bag mouth to an annular shoulder of a member which is held against the user's body by a belt. Such a construction is relatively complicated and is not suitable for mass-production. In addition, removal of a full bag without spillage will require care and skill, and especially for old or infirm patients there is still an unsatisfied need, despite the many attempts shown in the patent literature, for a design which allows quick and easy bag-changing with reduced risk of spillage.

According to the invention, there is provided a coupling for joining a pad or dressing to an ostomy bag including a first marker of closed loop form for defining a stoma aperture therein, the first member having a formation which defines two opposed walls, and a second member of closed loop form also defining a stoma aperture, the second member having a rib or projection dimensioned and positioned to fit between and resiliently bear against at least one of the walls when the members are connected in such a way as to make engagement with at least the said one wall.

The rib or projection may be gripped between the two walls of the second member in the mutually coupled positions of the members.

Preferably, one of the members is of channel form seen in cross-section and the other is dimensioned to be gripped between the mutually opposed channel walls.

The rib may, but need not necessarily have, a thin resilient deflectible seal strip extending therefrom which, when inserted in the channel, tends to spring outwardly to tightly engage one channel wall so improving

the sealing properties of the coupling. The seal strip may be, but need not be, integral with the rib or projection.

The first and/or second coupling member may be secured to or integral with one or more outwardly extending ears. These may be provided for one or both of two purposes, namely to afford attachment points for a belt by which the user holds the bag on his body and to provide accessible parts which the user can grip with his thumb and a finger to pull apart the interengaged first and second members, when the bag is to be replaced.

The first and second coupling members are preferably, but need not necessarily be of circular form. The second coupling member may have a flange which extends from the rib all the way round its periphery, and may be located on the radially inner or radially outer surface of the rib. The first and second coupling members may but need not be of low density polythene. The first coupling member may have a rim extending towards the interior of the channel and located at or near the free end of one of the channel limbs. This improves the mechanical security of the coupling. The rim is preferably on the radially outer limb of the channel.

The first or the second coupling member may be made integral with the pad or secured to it, for example by an adhesive. In the case of a particularly advantageous form of the invention, the pad is made of a plastic adhesive material comprising a blend of a water-soluble or water-swellable hydrocolloid and a water-insoluble, viscous elastic binder. Such a material may be cast or formed in a mould to surround and thus form an article effectively integral with the first or second coupling member as the case may be. The other coupling member may be made effectively integral with the bag. For example, when both the bag and the coupling member are of synthetic plastics material, the two may be heat-welded together or secured together by an adhesive.

Either or both of the coupling members may be injection moulded from any suitable synthetic plastics material.

The first or second coupling member may have a passageway leading from its interior to the exterior, and this passageway may contain a filter acting to reduce the odours in any gases which escape therethrough. The filter may be in the form of a replaceable cartridge containing carbon cloth. The cartridge may comprise a housing having an inlet and an outlet and at least one layer of carbon cloth disposed therein so that the gas in passing from the housing inlet to the outlet passes parallel to the surface of the layer. Advantageously, the housing may have a plurality of hollow pegs at one of its ends by which it is fixed into a holder located in the gas exit passageway, the interior of the pegs serving as the inlet.

The invention will be better understood from the following non-limiting description of an example thereof given with reference to the accompanying drawings in which:—

Figure 1 is an elevation view of a first embodiment of the invention, illustrating a first coupling member, looking in a direction outwardly from the user;

Figure 2 is a vertical axial section on the line II-II through the coupling member shown in Figure 1;

Figure 3 is an enlarged section taken in a vertical (or any radial) plane showing one form of rim construction on the member shown in Figures 1 and 2;

Figure 4 is an elevation view of one form of second coupling member, looking towards the user;

Figure 5 is a vertical axial section on the line V-V through the coupling member shown on Figure 4; and

Figure 6 is an enlargement of part of Figure 5; and

Figures 7 and 8 illustrate a second embodiment of the invention, which is a refinement of the embodiment shown in Figs 1-6. Figure 7 is an axial (or any radial) section through a modified first coupling member and Figure 8 is a similar section through a complementary second coupling member.

In Figures 1-6, ostomy bag is indicated at 10, Figure 2 and is secured by heat welding to a surface 12, facing away from the user, on the first coupling number 14. This is circular and defines an aperture 15 which in use surrounds the user's stoma. The aperture of course need not be circular but could be of any suitable shape. The second coupling member 16 (Figure 5) is made of two parts, preferably integral with each other, namely a flange 18 and a circular rib or projection 20 which co-operates with the channel-shaped first coupling member 14. The flange 18 has a circular aperture 22 and is intended to be secured to a pad or surgical dressing (not shown) which has a similar circular aperture and whose opposite surface contacts the skin of the patient. The pad may be a dressing as disclosed and claimed in British Patent No. 1088992.

Referring to Figure 3, the first coupling member 14 is of channel-shape seen in any radial cross-section and has a radially inner wall or limb 24 and a radially outer wall or limb 26. A rim 28 extends inwardly around the inner periphery of the wall 26 and, together with the wall 24, defines a restricted annular mouth or entry 28A into which, in use, the rib part 20 of the second coupling member 16 is pushed to firmly connect the first and second coupling members. Three ears 27 29, 30 (Figure 1) are secured to or moulded integrally with the channel and each may

serve to be gripped and pulled by the user when he wishes to separate the bag 10 from the pad. The ears 29 and 30 also serve for attachment of a belt if desired. For convenience of the user, the ear 28 may be located at any position around the axis and need not be at "12 o'clock" as illustrated.

The second coupling member 16 (Fig. 6) is principally in the form of a cylindrical rib 20 extending substantially perpendicularly from the flat flange 18, and includes a thin resilient flexible and deflectible seal strip 32. As shown, this is of tapering form seen in cross-section and extends at an angle radially inwardly from an inner surface 34 of the rib. In use, when the two coupling members are engaged, it springs radially inwardly to firmly engage the radially-inner wall 24 of the first coupling member to enhance the tight sealing properties of the coupling. Another surface 36 of the rib may be provided as shown with a peripheral rim 38 which co-operates with the rim 28 in providing mechanical security.

The seal strip 32 is illustrated as in one piece with the rib 20 but it could be a separate part adhesively or otherwise secured to the rib 20.

As seen in Figures 4 and 5, the second coupling member includes a passageway 40 by which gases can escape from the interior 22 of the coupling and hence from the interior of the bag when it is being worn by the user. The passageway 40 may contain filtering or deodorizing agents such as activated carbon, or fibrous active carbon cloth such as is described and claimed in British Patent No. 1 301 101. Other arrangements of vents and filters can be employed.

The arrangement illustrated in Figures 1-6 herein has the advantages of being light, inexpensive to manufacture, hygienic, secure and relatively easy to use.

Referring now to Figures 7 and 8, in this version of the invention, the cross-sectional profile of the first member is chosen such that there is an annular surface 60 inclined to the common axis of the coupling members and when the coupling members are connected, facing towards an opposite corner region of the channel section first coupling member. The second coupling member, that is to say the rib of closed loop form, also has an annular surface 76. The inclined annular surfaces 60, 76 are constructed to engage in face-to-face contact when the two coupling members are in their mutually coupled positions.

An important feature of the constructions so far described is that one coupling member has at least one pair of opposed walls between which a part of the other coupling member is trapped temporarily by the inherent resilience of the material, the latter being preferably low density polyethylene. A wide variety of profiles may be employed having this general characteristic.

The illustrated first coupling member 48 in Figure 7 has radially inner and outer limbs 50 and 52 joined by a radially extending web 54. The outer limb 52 has a rim 58, and this has an annular surface 60 at approximately 45° to the axis of the member 48.

The second coupling member 66 seen in Figure 8 is made of two parts, namely a rib 68 and an outwardly-extending flange 70. These are preferably but not necessarily integral. The second member may be moulded as a single moulding from synthetic plastics material such as low-density polyethylene. The pad or surgical dressing (not shown) which contacts the skin of the wearer is secured for example by heat welding or by adhesive to the surface 72 of the member 66. The rib 68 is of generally cylindrical form with a bead or rim 74 which has a flat annular surface 76 facing at an angle towards the flange 70. The surface 76 may be at about 45° to the axis of the coupling. A deflectible seal strip 78 engages the outer surface 80 of the inner wall 50 of the first coupling member 48.

The dimensions of the first and second coupling members, and in particular the width of the channel and the rib, the dimensions of the rim, and the material and dimensions of the peripheral seal strip 78 are all chosen to allow secure interconnection of the two coupling members in a gas-tight and liquid-tight manner, while allowing the user to manually separate the two members.

It will be appreciated that modifications are possible without departing from the invention. For example, the rim 58 could be placed on the radially inner wall 50 of the member 48, and the seal strip 78 and the rim 74 altered in position on the member 66. Alternatively the ostomy bag could be secured to the coupling member 48 and the pad secured to the coupling member 66. As yet further alternatives, in any of the above constructions, the seal strip 78 could be separate or separable from its associated coupling member, and it could be disposed on either the radially inner or outer surface of the rib, or on the radially inner or outer limb of the channel section member. The seal strip can be omitted if the rib is a tight fit in the channel.

The reader is referred to the description and claims of Application No. 1242/79, which is divided out of the present application. The reader is also referred to Applications 44096/79 and 44097/79 which were likewise divided out.

WHAT WE CLAIM IS:—

1. A coupling for joining a pad or dressing to an ostomy bag including a first member of closed loop form for defining a stoma aperture therein, the first member having a formation which defines two opposed walls,

and a second member of closed loop form also defining a stoma aperture, the second member having a rib or projection dimensioned and positioned to fit between and resiliently bear against at least one of the walls when the members are connected in such a way as to make sealing engagement with at least the said one wall.

2. A coupling according to claim 1 in which the rib or projection is gripped between the walls.

3. A coupling according to claim 1 or 2 in which each coupling member is of resilient synthetic plastics material.

4. A coupling according to any preceding claim in which one of the coupling members is of channel form seen in cross-section and the other is dimensioned to be gripped between the mutually opposed channel walls.

5. A coupling according to any preceding claim in which the first member is secured to the bag and the second member is secured to the pad or dressing.

6. A coupling according to any one of claims 1-4 in which the first member is secured to the pad or dressing and the second member is secured to the bag.

7. A coupling according to claim 5 or claim 6 in which the members are respectively secured by heat welding.

8. A coupling according to claim 5 or 6 in which the members are respectively secured by adhesive.

9. A coupling according to any preceding claim in which the aperture is generally circular and the two opposed walls are generally annular in form.

10. A coupling according to any preceding claim in which the rib or projection has a thin resilient deflectible seal strip extending therefrom, which, when the rib or projection is disposed between the walls, springs away therefrom to sealingly engage one of the walls.

11. A coupling according to any one of claims 1-9 in which one of the walls has a thin resilient deflectible seal strip extending therefrom which, when the rib or projection is inserted between the walls, springs outwardly to engage the rib or projection.

12. A coupling according to any preceding claim in which the one of the members that is secured to the bag has one or more radially outwardly extending ears.

13. A coupling according to any preceding claim in which one or both of the members is made of low density polyethylene.

14. A coupling according to claim 5 or 6 in which the pad or dressing is made of a plastic adhesive material comprising a blend of a water-soluble or water-swellable hydrocolloid and a water-insoluble, viscous elastic binder.

15. A coupling according to any preceding claim in which one of the coupling members defines a gas exit passageway leading from the aperture to the exterior.

16. A coupling according to claim 15 in which the gas exit passageway contains a filter.

17. A coupling according to claim 16 in which the filter is in the form of a replaceable filter cartridge.

18. A coupling according to claim 17 in which the cartridge comprises a housing having an inlet and an outlet and at least one layer of carbon cloth disposed therein so that the gas in passing from the housing inlet to the outlet passes parallel to the surface of the layer.

19. A coupling according to claim 18 in which the housing has a plurality of hollow pegs at one of its ends by which it is fixed into a holder located in the gas exit passageway, the interior of the pegs serving as the inlet.

20. A coupling according to claim 4 or any claim dependent thereon in which the rib or projection has a peripheral bead extending therefrom in a direction towards the inner or outer wall of the channel, the inner or the outer wall as the case may be having a complementary bead positioned to improve the mechanical security of the coupling.

21. A coupling according to claim 20 in which each of the two beads has an annular surface thereon inclined to the common axis of the coupling members when connected, the arrangement being such that the two annular surfaces are in face-to-face contact when the two members are in their mutually coupled positions.

22. A coupling substantially as herein described with reference to, and as illustrated in, Figures 1-6 of the accompanying drawings.

23. A coupling substantially as herein described with reference to, and as illustrated in, Figures 7 and 8 of the accompanying drawings.

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1571657 COMPLETE SPECIFICATION
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Sheet 1

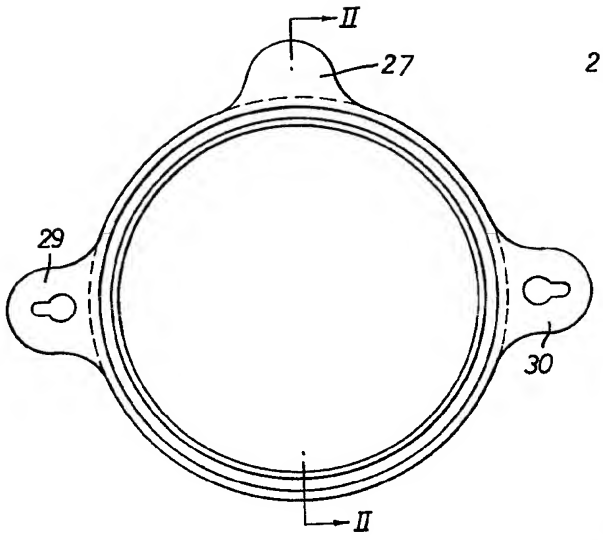

FIG. 1

FIG. 2

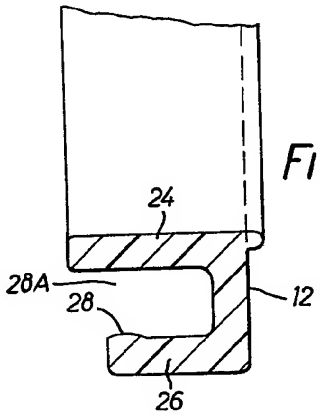

FIG. 3

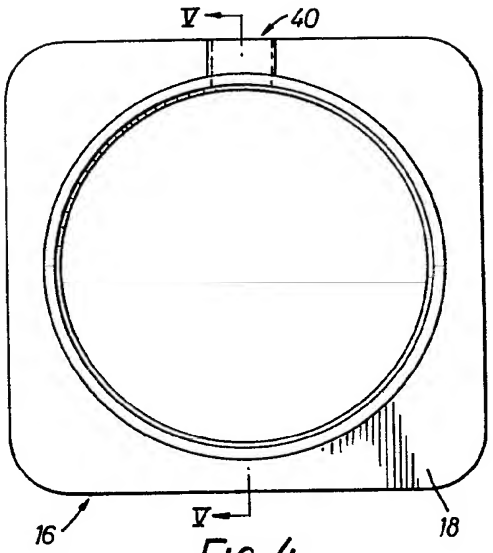

FIG. 4

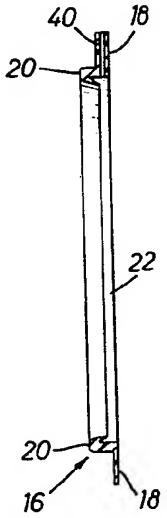

FIG. 5

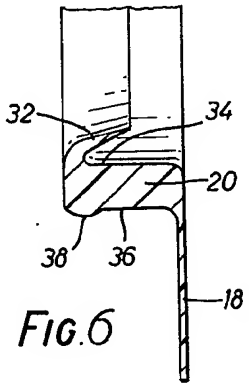

FIG. 6

1571657 COMPLETE SPECIFICATION
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Sheet 3

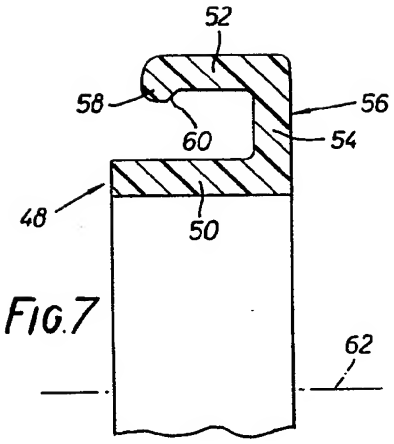

FIG.7

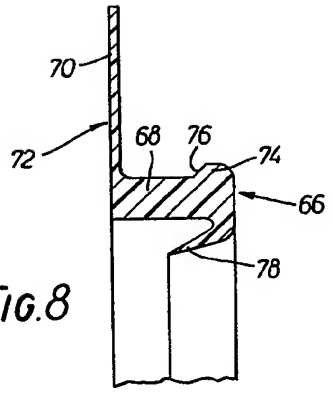

FIG.8